

**TRANS-SEPTAL SHEATH WITH SPLITTING DILATING NEEDLE
AND METHOD FOR ITS USE**

FIELD OF THE INVENTION

5 The present invention is directed to a device that functions as both a guiding sheath and dilating needle.

BACKGROUND OF THE INVENTION

 Electrophysiology catheters are commonly used for mapping electrical activity in a heart.
10 Electrophysiology is a specialty within the field of cardiology for diagnosis and treatment of electrical abnormalities of the heart. By mapping the electrical activity in the heart, ectopic sites of electrical activation or other electrical activation pathways that contribute to heart malfunctions may be detected. This type of information may then allow a cardiologist to intervene and destroy the malfunctioning heart tissues. Such destruction of heart tissue is
15 typically performed using an ablation catheter and is referred to as ablation. Ablation is a rapidly growing field within electrophysiology and obviates the need for maximally invasive open heart surgery.

 Occasionally, an electrical abnormality occurs in a location that is difficult to reach with standard catheter capabilities. A left atrium of a heart is one such location. When an electrical
20 abnormality occurs in a left atrium, a dilation catheter, or dilator, may be inserted percutaneously, fed through one or more major blood vessels, and inserted into a right atrium of the heart. A needle may then be feed through the dilator and inserted into and through the atrial septum to puncture the atrial septum to allow access to the left atrium for a therapeutic catheter, such as an ablation catheter.

25 A current technique for puncturing the atrial septum includes positioning a dilator adjacent to an area of the atrial septum that is desired to be punctured (typically at the fosa ovalis), inserting a separate needle into the dilator, feeding the needle through the dilator until the needle protrudes beyond the dilator, and puncturing the atrial septum with the needle. This technique has several disadvantages. For example, locating the desired puncture site and then
30 inserting and feeding a separate needle into the dilator increases the procedure time, and increases the likelihood that the dilator will be inadvertently moved before the needle reaches the desired puncture site, thus requiring a repositioning of the dilator. If the repositioning is

performed with the needle inside the dilator, the possibility exists for the needle to slide out of the dilator and damage venous or atrial structures. If the needle is removed during repositioning, procedure time is again extended during reinsertion and re-feeding of the needle into the dilator, and an inadvertent movement of the dilator during reinsertion and re-feeding of the needle again exists.

Another more serious disadvantage of the current technique is that, to dilate the hole enough for a guiding sheath to fit through with the dilator, the sharp needle has to be advanced ten to twenty millimeters into the left atrium, which would bring the sharp edge dangerously close to the superior wall of the left atrium, which might result in perforation, especially if the left atrium is small. Moreover, a force in a distal direction is required to insert the needle into and through the atrial septum, yet there is no means for controlling the maximum protrusion of the needle from the dilator. As a result, a tendency is for the operator to continue to apply a forward force to the needle even after the needle has crossed the atrial septum, thus risking damage to venous or atrial structures in the left atria or even cardiac puncture if the needle protrudes too far from the dilator.

Yet another disadvantage of the existing technique is that, when the sheath is advanced into the left atrium, it is typically placed at least about ten millimeters beyond the septum wall. If it is advanced less than ten millimeters, it might fall out of the left atrium. This gives catheters and other devices that go through the sheath very limited access to the septum from the left side. If a procedure requires mapping or ablation on the left septum, it is almost impossible to perform with conventional sheaths.

SUMMARY OF THE INVENTION

The present invention addresses the above-referenced problems by providing a device useful for accessing the left atrium. The device comprises an elongated tubular body and a dilating tip. The tubular body has an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough. The dilating tip is slidably mounted on the distal end of the tubular body. The dilating tip comprises a segmented surface that is generally transverse to the axis of the tubular body, and a generally rigid tube extending distally from the segmented surface and having a sharp distal end. Distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface to thereby open the segmented surface.

In another embodiment, the invention is directed to a device useful for accessing the left atrium comprising an elongated tubular body and a dilating tip. The tubular body has an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough. The dilating tip is slidably mounted on the distal end of the tubular body. The dilating tip comprises a ring mounted in surrounding relating to the distal end of the tubular body and a segmented surface that is generally transverse to the axis of the tubular body. The segmented surface comprises three or more segments, each segment being hingedly attached to the ring. The dilating tip further comprises a generally rigid tube extending distally from the segmented surface. The tube has a sharp distal end and is segmented into three or more segments. Distal movement of the tubular body relative to the dilating tip exerts a force on the segmented surface to thereby open the segmented surface.

In another embodiment, the invention is directed to a method for accessing the left atrium of a patient. The method comprises inserting the dilating tip of a device as described above into the right atrium of the patient. The atrial septum is punctured with the tube of the dilating tip to create a trans-septal hole. The tubular body is advanced distally relative to the dilating tip to open the segmented surface and introduce a distal portion of the tubular body into the left atrium through the trans-septal hole.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view of a device according to the invention;

FIG. 2 is a side view of a dilating tip according to the invention;

FIG. 3 is a side view of the dilating tip of FIG. 2 turned 90°;

FIG. 4 is a perspective view of a dilating tip mounted on the distal end of a tubular body, where the dilating tip is slightly open; and

FIG. 5 is a perspective view of a dilating tip mounted on the distal end of a tubular body, where the dilating tip is almost entirely open.

DETAILED DESCRIPTION OF THE INVENTION

The invention is directed to a device that serves as a guiding sheath, a dilator and a dilator needle. The device comprises a generally-flexible elongated tubular body **10** having proximal and distal ends and a lumen **12** extending longitudinally therethrough. In the depicted embodiment, the lumen **12** is a central lumen. The tubular body **10** can be of any suitable construction. Preferably the tubular body **10** comprises polyethylene with barium sulfate. If desired, a lubricious coating can be provided inside or over the tubular body **10**. A suitable coating comprises silicone, such as MDX4-4159, a mixture of aminofunctional polydimethylsiloxane copolymer in mixed aliphatic and isopropanol solvents (commercially available from Dow Corning™, Midland, Michigan).

The tubular body **10** has an outer diameter ranging from about 2 mm to about 4 mm, preferably from about 2.5 mm to about 3.5 mm, still more preferably about 3 mm. Preferably the tubular body **10** has a length ranging from about 60 cm to about 100 cm.

On the distal end of the tubular body **10** is slidably mounted a dilating tip **14**. As shown in FIGs. 2 to 5, the dilating tip **14** comprises a segmented surface **16** that is generally transverse to the axis of the tubular body **10**, and a generally rigid tube **18** extending distally from the segmented surface. In the depicted embodiment, the dilating tip **14** is generally funnel-shaped with the segmented surface **16** being generally round and angled from its outer edge to its center, as best shown in FIGs. 2 and 3. The depicted segmented surface **16** comprises three pie-shaped segments **20**, all of equal size. As will become apparent, the precise number, shape and size of the segments **20**, as well as the overall shape of the dilating tip, can vary as desired. For example, the segmented surface **16** can be generally flat rather than angled, although the angled surface is particularly desirable for dilating the septum once the septum has been punctured, as described further below.

Preferably the dilating tip **14** is made from a material having shape memory. A particularly suitable material for this purpose is a memory alloy of a nickel-titanium composition known as nitinol. Type 55 nitinol, made of 55% by weight nickel and 45% titanium, and type 60 nitinol, made of 60% by weight nickel and 40% titanium, as well as various ternary and quaternary compositions of nitinol, can be used in the invention.

The dilating tip **14** further comprises a ring **22** slidably mounted over the outside of the tubular body **10** to which the segments **20** are attached. In the depicted embodiment, each of the segments **20** has an outer edge **21** that is hingedly attached to the ring **22** at a hinged junction **24**.

The segments **20** each also have two free edges **23** that are not attached to any of the other segments or to the ring **22**. The ring **22** preferably has an inner diameter slightly greater than the outer diameter of the tubular body **10**, and the inner diameter preferably ranges from about 2 mm to about 3 mm. As the ring **22** is moved proximally relative to the tubular body **10**, the distal end
5 of the tubular body contacts the inner surfaces of the segments **20** of the segmented surface **16**, thereby pushing the segments distally **20**. Because only the outer edges **21** of the segments **20** are hingedly attached to the ring **22**, the tubular body **10** pushes the segments open, as best shown in FIG. 5.

As noted above, an elongated generally rigid tube **18** extends distally from the segmented
10 surface **16**. As best shown in FIG. 2, the generally rigid tube **18** has a sharp distal end **24**. As used herein, the terms "generally rigid" and "sharp" when referring to the tube **18** and distal end **24**, respectively, mean that the tube is sufficiently rigid and the distal end is sufficient sharp so that the tube can be used to puncture the septum, as described in more detail below. In the depicted embodiment, the tube **18** is depicted as generally cylindrical, but other shapes are
15 contemplated within the invention, such as a tube having a generally square or hexagonal cross-sectional area. The tube **18** preferably has a length ranging from about 2 mm to about 6 mm, more preferably from about 3 mm to about 5 mm. The tube **18** preferably has an outer diameter ranging from about 0.6 mm to about 1 mm, more preferably from about 0.7 mm to about 0.8 mm.

In the depicted embodiment, the tube **18** is also segmented into three tube segments **26**. Each tube segment **26** has a proximal end attached to a segment **20** and a free distal end. With this design, when the tubular body **10** is moved distally to open the segments **20**, the tube segments **26** also separate and open with the segments **20**. Other arrangements are contemplated within the scope of the invention. For example, the tube **18** could be a unitary (non-segmented)
20 structure that is attached to only one of the segments **20**.

In the depicted embodiment, the distal end of the tubular body **10** is generally straight. However, in some instances it may be advantageous for a portion of the distal end of the tubular body **10** to have a pre-formed curve. For example, due to the angle of the right atrium opening with respect to the atrial septum, when a tubular body **10** having a straight distal end is inserted
30 into the right atrium and advanced to a position adjacent to the atrial septum, the tube **18** is likely to be angled with respect to the atrial septum. In such an instance, it may be desirable for the distal end of the tubular body **10** to have a pre-formed curve to allow the tube **18** to be situated in

a more perpendicular arrangement relative to the atrial septum, thus allowing for a cleaner puncture of the septum.

In order to facilitate relative movement of the tubular body **10** relative to the dilating tip **14**, a slidable ring **28** or other slidable member is mounted on the proximal end of the tubular body. The slidable ring **28** is connected to the ring **22** of the dilating tip **14** with a plurality of wires **30**. Thus, in use, the physician can pull the slidable ring **28** proximally relative to the tubular body **10**, thereby pulling the dilating tip **14** proximally relative to the tubular body, and thus opening the segmented surface **16** of the dilating tip. Other mechanisms for facilitating relative movement of the tubular body **10** and dilating tip **14** are considered within the scope of the invention.

In the depicted embodiment, a latch mechanism is provided to hold the slidable ring **28** in place relative to the tubular body **10** when the dilating tip **14** is in an open position. The latch mechanism includes one or more latches **32** that are fixedly attached to the proximal end of the tubular body **10** proximal to the slidable ring **28**. The latches **32** are received by notches **34** in the slidable ring **28**, to thereby temporarily lock the slidable ring in place. The presence and arrangement of the latch mechanism is not critical to the invention.

Additionally, a pressure valve **36** is mounted on the proximal end of the on the tubular body **10** such that the pressure in the tubular body may be monitored, as discussed further below.

In use, a guidewire (not shown), such as a .032 inch diameter guidewire, is positioned within the right atrium of a patient's heart. The device of the invention is then passed over the guidewire, with the guidewire extending through the lumen **12** of the tubular body **10** and through the elongated tube **18**. The guidewire preferably includes an atraumatic distal tip.

The distal end of the device is passed over the guidewire and introduced into the right atrium. If desired, the dilating tip **14** and/or the distal end of the tubular body **10** can comprise tungsten or other radiopaque material, which appears dark under fluoroscopy, allowing the distal end of the device to be easily viewed under fluoroscopy. Once the dilating tip **14** is in the right atrium, a puncture site may be located. The limbus of the fossa ovalis provides a good reference point for locating an optimal puncture site. Often, the ridge of the limbus of the fossa ovalis can be felt by the operator using the distal end of the dilating tip **14**. Just below the limbus is the central atrial septum, which tends to be the thinnest area of the septum, and is therefore the preferred area to penetrate. When the central atrial septum is located with the dilating tip **14**, the

tube **18** may be placed directly adjacent to and abutting the central atrial septum and pushed distally against the septum to thereby puncture of the septum.

As noted above, the proximal end of the tubular body **10** may be attached to a pressure valve **26** such that the pressure in the tubular body may be monitored. The pressure in the right atrium is different then the pressure in the left atrium. Therefore, by monitoring the pressure in the tubular body **10**, the operator can determine when the needle has entered the left atrium, as is generally known in the art.

Once the tube **18** of the dilating tip **14** is in the left atrium, the slidable ring **28** on the proximal end of the tubular body **10** is moved distally relative to the tubular body. As a result, the distal end of the tubular body **10** is moved distally relative to the dilating tip **14** to thereby push open the segmented surface **16**. This action dilates the trans-septal hole created with the tube **18** to thereby permit the distal end of the tubular body to be introduced into the left atrium. Alternatively, the segmented surface **16** can be moved distally into the left atrium to dilate the trans-septal hole, particularly when the segmented surface is angled as shown in FIGs. 2 and 3, before the tubular body **10** is moved distally to open the segmented surface.

Once the segmented surface **16** is opened within the left atrium, the latches **32** can then be used to maintain the slidable ring **28** in place so that the dilating tip **14** is kept in an open configuration. If the slidable ring **28** is not locked in place, the tubular body **10** may tend to slip proximally out of the left atrium. With the distal end of the tubular body **10** within the left atrium, the tubular body may then be used to guide a therapeutic catheter, such as an ablation catheter, into the left atrium. Thus, the tubular body **10** serves as a guiding sheath for this purpose.

The inventive device offers numerous advantages over devices previously used for trans-septal access. Notably, the inventive device avoids the need for a needle and dilator, as all of the functions are performed by the single device of the invention, thereby simplifying the process. In contrast, traditional methods require at least three different devices working together, thereby requiring numerous exchanges and management of fluids aspiration and pressure monitoring through more than one lure. The inventive device also avoids the need to change the pressure monitoring from a needle to a sheath.

Further, the limited length of the tube **18** avoids damage that can typically be caused when a needle is used and advanced too far into the left atrium. Additionally, the dilating tip **14**, when in an open position, acts as a backstop to prevent the tubular body **10** from falling out of

the left atrium. Therefore, it is not necessary to advance the tubular body **10** as far into the left atrium as is required with traditional guiding sheaths. As a result, the tubular body **10**, which serves as a guide mechanism for a treatment catheter, does not significantly interfere with the operator's ability to manipulate the treatment catheter within the left atrium. In particular, the treatment catheter can be used to access more of the left atrium than with a traditional guiding sheath.

The preceding description has been presented with references to presently preferred embodiments of the invention. Persons skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structures can be practiced without meaningfully departing from the principle, spirit and scope of this invention. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and shown in the accompanying drawings, but rather should be read as consistent with and as support for the following claims, which are to have their fullest and fairest scope.